

## peer review notes

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### In this Issue

- New Webinars to Connect Applicants to NIH Peer Review Experts
- CSR Is Facing a Surge in Applications
- Top 10 Things You Should Not Say in a Review
- End of an Era: CSR Accepts the Last Paper Applications
- CSR Names Winners of its America COMPETES Challenges to Maximize Fairness in NIH Peer Review
- Big Data Centers Applications = Big Job for Reviewers and NIH
- Systematic Application Compliance Checking—What It Is and What It's Not

# New Webinars to Connect Applicants to NIH Peer Review Experts



Pass the word to applicants and those who mentor them: the NIH Center for Scientific Review will host four Meet the Experts in NIH Peer Review Webinars in early November 2014 to give new NIH grant applicants and others useful insights into the submission and review processes.

CSR is the portal for NIH grant applications and their review for scientific and technical merit.

### Webinars Will Each Focus on a Different Type of NIH Grant Application

Webinar Focus	Date
Academic Research Enhancement Awards (R15)	Nov. 4, 2014
Fellowship Awards	Nov. 5, 2014
Small Business Grants (SBIR/STTR)	Nov. 7, 2014
Research Project Grants (R01)	Nov. 10, 2014

All of the Webinars will run from 2:00 to 4:00 p.m. EST, including a 30 minute Q&A period.

### Viewers Will See Presentations by Five CSR/NIH Experts

- The Review of Your NIH Grant Application Begins Here
- What You Need to Know about Application Receipt and Referral
- How Your Application Is Reviewed
- Key Things to Know About Your Type of Application (See above list.)
- Jumpstart Your Career with CSR's Early Career Reviewer Program

### **How to Participate in the Webinar**

- Go to <u>www.csr.nih.gov/webinar</u> to register for the Webinar you wish to join before Tuesday, October 28. You will not need to download special software. You will just need a reliable Internet browser and connection.
- **Submit questions for the Q&A session before or during the Webinar** by sending them to the moderator at <a href="mailto:AskExperts@csr.nih.gov">AskExperts@csr.nih.gov</a>.
- **Go to** <u>www.csr.nih.gov/webinar</u> on the day/time your Webinar is scheduled to run and click on the link that will be provided there.
- View archived copies of each Webinar via the <u>Webinar webpage</u>. The recordings should be posted within a week after broadcast.

If you have general questions about the NIH application and review processes at other times, please visit the  $\underline{\text{CSR}}$  website or the  $\underline{\text{NIH Grants and Funding}}$  website. The  $\underline{\text{NIH Information Service}}$  can address specific questions.

### **CSR Is Facing a Surge in Applications**



"Total numbers of applications going to CSR study sections have surged about 14 percent," said CSR Director Dr. Richard Nakamura. "The NIH Office of Extramural Research reports about a 10 percent increase in research project grant applications across NIH."

"It's clear a large part of this increase is due to NIH removing limits on resubmitting the same research idea," he said. "The new policy was designed to keep alive worthy ideas that would

have been funded had the NIH budget kept up with inflation."

Why are CSR and OER numbers different? The types of applications CSR reviews have experienced greater increases than others. In addition, CSR is reviewing a slightly larger portion of NIH applications (79%) now than before.

"The new wave of applications brings added burdens," said Dr. Nakamura. "We've had to call in more reviewers and hire more staff. If the increase in applications doesn't subside, we'll be facing a more difficult situation. Success rates -- which are at historic lows -- will go down further, and finding highly qualified scientists to review applications will become more difficult than it is now."

"We will closely monitor the situation and explore our options," he said. "In the meantime, we encourage applicants to use common sense when they decide to resubmit an application. An application that was unsuccessful before will most likely need to be significantly enhanced to make the effort of resubmitting it worthwhile."

### **Summary of the New Policy**

As we explained earlier in the <u>spring</u>, NIH responded to community appeals by <u>eliminating its policy</u> that allowed researchers only one resubmission if their initial grant application was unsuccessful. Tight budgets turned a policy meant to cut the wait time for funding into a barrier that prevented further review and funding of valuable research. Now, there is no limit to the number of times a research idea can be submitted, and a subsequent application may be submitted as an A1 resubmission or a new (A0) application.

#### **What Applicants Need to Know**

- Your new (A0) application cannot include any reference to a previous review. Existence of any of the following in your application materials is unacceptable and could lead to withdrawal of your application: the previous overall impact score or individual criterion scores, reviewers' comments, or information on how your application was changed since your last submission—including special formatting to mark those changes.
- Your application submitted after an unsuccessful renewal resubmission (A1) application must be submitted as new (policy unchanged). You can present your progress as preliminary data in support of your new (type 1) application, but you cannot include a formal Progress Report or Progress Report Publication List. Note that a phase II SBIR or STTR application is actually a renewal of the phase I application, and so this requirement also applies to applications following an unfunded, resubmitted SBIR/STTR phase II application, where allowable type 1 applications include a new Phase I application, new Fast Track application, or a new Direct to Phase II application (only if the phase I goals were accomplished without NIH funding).

 Your summary statement should be issued before you submit a subsequent version of that application. NIH expects you will take advantage of the feedback to refine and strengthen each subsequent submission of that application.

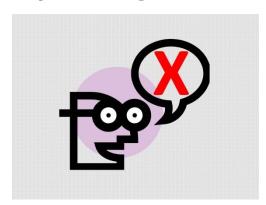
#### What Reviewers Should Know

- Review a new application as a new application, even if you recall having reviewed an earlier version.
- **Do not recycle old critiques for applications you've reviewed before.** It is likely the application has been refined and strengthened since its last submission and is not the same.

### **Looking Forward**

"While the fundamental challenge remains the tight NIH budget, we hope that relaxing the resubmission policy will help applicants put forward their very best application," said Dr. Nakamura.

### Top 10 Things Reviewers Shouldn't Say



"Our reviewers, chairs and scientific review officers do tremendous jobs," said CSR Director Dr. Richard Nakamura. "They know what's at stake, and the care and commitment they show are impressive. However, every once in a while we hear a reviewer say something they shouldn't."

To help everyone stay in tune, we pulled together the following list of things reviewers shouldn't say:

1. "I didn't read the application, but I scanned it and saw the applicant said XXX. He doesn't know what he's doing."

Damning statements like this can skew a review discussion over something that might be insignificant in the context of the overall application. It's better for you to ask other reviewers who have read the application carefully what they think about XXX.

2. "This New Investigator does not appear to be fully independent since he continues to co-publish with his fellowship mentor/department chair, or does not have designated lab space, or has not been promoted in the past several years."

Academic research organizations have widely diverse policies for faculty advancements and lab space, and many PIs maintain productive and healthy collaborations with mentors for many years after establishing themselves as bona fide investigators. You should focus more on the investigator accomplishments, such as being the first or senior author on a significant publication or giving presentations at major scientific meetings.

### 3. "This application is not in my area of expertise . . . "

If you're assigned an application you feel uncomfortable reviewing, you should tell your Scientific Review Officer as soon as possible before the meeting.

### 4. "I don't see this basic science research affecting my clinical practice any time soon."

An application does not necessarily have to show the potential for clinical or timely impact—if the applicant doesn't make such claims. Basic research often takes time to pay off, and you're charged to assess the "likelihood for the project to exert a sustained, powerful influence on the research field(s) involved." Absence of an effect on public health does not necessarily constitute a weakness in basic science.

## 5. "I like this project but I'm giving it a poorer score because the applicant has too much money."

Other funding is not a scoreable matter. You should focus on the application's scientific and technical merit. However, you can note an excessive budget request in the budget section for NIH to consider.

### 6. "This application has 2 great aims and 1 bad one. I would recommend deleting Aim 3, and I can give it a 1 or 2."

You cannot trade aims with scores. The application needs to be evaluated as a whole.

## 7. "This R21 application does not have pilot data, which should be provided to ensure the success of the project."

R21s are exploratory projects to collect pilot data. Preliminary data are not required, although they can be evaluated if provided.

## 8. "The human subject protection section does not spell out the specifics, but they already got the IRB approval, and therefore, it is ok."

IRB approval is not required at this stage, and it should not be considered to replace evaluation of the protection plans.

### 9. "This application was scored a 25 and 14th percentile last time it was reviewed . . . ."

You should not mention the previous score an application got, because this could skew the review discussion. Focus on the strengths and weaknesses of the current application as well as the responses to previous critiques.

### 10. "This is a fishing expedition."

It would be better if you said the research plan is exploratory in nature, which may be a great thing to do if there are compelling reasons to explore a specific area. Well-designed exploratory or discovery research can provide a wealth of knowledge.

### **End of an Era: CSR Accepts the Last Paper Applications**



After a monumental 10-year effort by NIH staff, the Center for Scientific Review accepted the last paper applications for NIH this past May. It was a day that passed quietly -- nothing like the good ole days.

On big receipt days, you'd see two or three tractor-trailer trucks competing with smaller delivery trucks to get to one of CSR's three delivery bays. The boxes would be thrown into large mail carts, which would pile up outside the x-ray screening room before the applications were stacked to the ceiling in a storage room.

The last paper applications were for complicated cooperative agreement grants (UM2) from the National Institute for Allergy and Infectious Diseases: <u>Accelerating Medicines Partnership in Rheumatoid Arthritis and Lupus: Network Leadership Center.</u>

Like the Big Data Center applications we discussed <u>below</u>, the applications for these Network Leadership Center grants were very large and involved multiple sites and many investigators.

#### **More Benefits to Come**

It is hard to calculate all the benefits of going paperless. We have certainly saved untold acres of trees, and applicants together have probably saved several millions of dollars by not having to ship paper applications to NIH. But there are more benefits to come.

NIH developed a new on-line submission tool called <u>ASSIST</u> to accommodate the electronic submission of our multi-project applications. NIH was able to build many improvements into ASSIST that had been long requested by the community. We expect all applicants to be able to benefit from the new system very soon, as we are busy making the necessary changes to allow applicants to use ASSIST for all types of NIH grant applications.

# CSR Names Winners of its America COMPETES Challenges to Maximize Fairness in NIH Peer Review



CSR recently named the winners of its two America COMPETES Act challenges to help identify new methods to detect bias in peer review and identify strategies to strengthen fairness and impartiality in peer review. This effort to study the possibility of bias is part of a much larger NIH effort to respond to the study that showed Black applicants for NIH grants do not fare as well as White applicants after researchers controlled for various factors.

"We are pleased to announce four winners, who submitted ideas that NIH may help further develop and pursue," said Dr. Nakamura, CSR Director. "These ideas will strengthen the science for tackling disparities in grant awards. Doing so is critical to moving forward, because you can't fix such a problem if you don't have validated ways to diagnose and address it."

"Many of the entries overlapped approaches that had recently been <u>proposed</u>, which was gratifying. It suggests we are on the right track." He then explained that "The winning entries were recognized for proposing new ideas and creative elements to approaches we are pursuing."

**Learn About the Winners and Their Interesting Ideas** by viewing our <u>news flash</u>.

### **Creating a Robust Judging Process for Entries**

"There are many individuals who made this competition possible," said Dr. Nakamura. He noted that Dr. Monica Basco, who led CSR's Challenge initiative, carefully designed and coordinated a two-stage judging process to maximize the rigor and fairness of the award process. Each of the 82 entries was anonymized before being reviewed for scientific and technical merit based on pre-determined criteria by a panel of experts in fields relevant to peer review, reviewer bias, and evaluation and training methods. These experts are members of the <u>ACD Diversity Working Group Subcommittee</u> on Peer Review.

Finalists were identified and further evaluated by a panel of judges from the National Science Foundation and NIH who looked at the entries for their technical merit, creativity, and potential for helping NIH address key issues related to fairness and impartiality in peer review.

# **Big Data Centers Applications = Big Job for Reviewers and NIH**



NIH recently launched an <u>initiative</u> to enable the biomedical research community to address the awesome opportunities and challenges of doing research with big biomedical and behavioral data sets. One critical step was to solicit applications for Big Data to Knowledge (BD2K) Centers of Excellence for developing new infrastructure, methodologies and techniques to integrate, process, transmit, handle and analyze large and diverse data sets.

#### The Excitement

The initiative generated lots of excitement. All the NIH institutes and centers committed funds to support it, and more than 1,000 researchers at the PD/PI or coinvestigator level from about 200 institutions submitted 108 applications.

It also generated lots of work. The applications generated about 4,000 conflicts because each application typically had 20 investigators at 6-7 institutions, and there were numerous letters of support. On top of this, the applications were among the last paper applications submitted to NIH. Each one weighed in at 500-700 pages. Identifying conflicts by hand was a monumental task.

#### **CSR Finds a New Way to Review**

CSR had to develop a two-stage process to review these applications. Sixty reviewers were recruited to participate in both stages. In stage one, each application was assigned to five reviewers, who reviewed their applications online and assigned them to one of three categories: should be discussed, may be discussed, or should not be discussed. Reviewers also wrote short critiques.

In stage two, the applications that merited further review went to one of three special review groups, which scored each of the five sections of the applications and discussed the top applications at face-to-face meetings. It typically took about an hour to discuss and score each application, and the summary statements for the discussed applications ran 20-25 pages.

#### **Better Than Expected**

"It was amazing how willing the reviewers were," said Dr. Ray Jacobson, who coordinated these reviews with Drs. Allen Richon, Nick Gaiano, and Feng Tao. "The cooperation between CSR and program officials also was really good, and the many members of our support staff who assisted were invaluable. It was a great team, and things went smoothly."

More amazing was the breadth and promise of the applications. They proposed new ways for harvesting insights from data that are flowing from most areas of biomedical research by developing novel methods and tools that will allow the biomedical community to share, access and better interpret the massive amounts of imaging, genomic, clinical, and mobile health data being generated every day by ongoing research efforts funded by the NIH.

However, the most satisfying part for all involved is that NIH was so taken with the top applications that it funded 11 centers—3 to 5 more than planned.

# Systematic Application Compliance Checking—What It Is and What It's Not



Automated enforcement of business rules by NIH eRA systems plays an important role in the application submission process – it helps you and it helps NIH.

Understanding what that role covers can be the difference between your application moving forward to review and not.

To find out what you need to know, check out the recent article the eRA Commons team has posted: Systematic

<u>Application Compliance Checking – What It Is and What It's Not</u>. eRA Commons is part of the NIH Office of Extramural Research.

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